GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4647
ANSWERED ON:19.12.2001
TRIAL REPORT ON NET-N
MINATI SEN;MOHAN PONNUSWAMY

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government have got any international trial reports on Net-N;

(b) if so, action strategy of Government if any serious side effects are reported in any case;

(c) whether the long acting injectable contraceptives are not recommended in any Medical text books as a standard procedure, till date;

(d) if so, the Government contemplating/thinking it to introduce as such;

(e) whether there is any report of this drugs on non-human experiments;

(f) the Pharmaceutical companies or commercial institutions behind such trial programmes;

(g) whether in early 80`s the phase 3 trial of ICMR was discontinued due to serious side effects; and

(h) if so, details of the rational instituting such trial again?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR)

(a): Yes, Sir. The NET EN is an injectable contraceptive containing 200 mg./ml. of Norethendrone EnanthaneReview of all available national and international literature in both developed and developing countries on pre-clinical and clinical experiences of use of a particular drug/device is done before a clinical trial with the drug is conducted in the country.

NET EN 200 mg two monthly injectable contraceptive is registered in over 60 countries; available in both public and private sector and there are more than 1 million women using this contraceptive.

(b): No serious side effects have been reported with the use of NET EN 200 mg two monthly injectable contraceptive in studies conducted in India or globally. The commonest side effects in the form of menstrual abonormalities including amenorrhoea, are transient in nature and disappear after the treatment is discontinued. This contraceptive is available through the private sector in the country where women desiring of using this method can obtain it on the prescription of a qualified medical doctor (Gynecologist).

(c): Long acting injectable contraceptives are included in the list of available options for contraceptives in the standard Medical text books.

(d): Does not arise.

(e): Based on animal studies, the Toxicology review panel of WHO has recommended that current and planned studies of NET-EN could continue and that it could be introduced into Family Planning Programmes.

(f): The injectables in the clinical trials carried out by the ICMR were provided by the Special Programme for Research in Human Reproduction, World Health Organizaton, Geneva. The drug is being marketed by M/s German Remedies in India.

(g): No sir, the ICMR phase III trial was not discontinued due to serious side effectsNET EN was evaluated for its efficacy as a two monthly or three monthly injectable contraceptive and NET EN was found to be efficacious as a two monthly injectable contraceptive.

(h): No applicable. The present study to be conducted by the Institute of Research and Reproduction, Mumbai, an ICMR research Institute is aimed to assess the demand/acceptability and logistical requirements for NET EN 200 mg two monthly injectable

contraceptive under programme condition.